General

Guideline Title

Tobacco treatment.

Bibliographic Source(s)

University of Michigan Health System. Tobacco treatment. Ann Arbor (MI): University of Michigan Health System; 2012 Mar. 16 p.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Smoking cessation. Ann Arbor (MI): University of Michigan Health System; 2006 Aug. 12 p. [1 reference]

Recommendations

Major Recommendations

Note from the University of Michigan Health System (UMHS) and the National Guideline Clearinghouse (NGC): The following guidance was current as of March 2012. Because UMHS occasionally releases minor revisions to its guidance based on new information, users may wish to consult the original guideline document for the most current version.

Note from NGC: The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, duration, and instructions for nicotine replacement therapies, bupropion, and varenicline; cost of drugs; counseling and motivational interventions; and considerations for special populations (i.e., pregnant and breastfeeding patients, racial and ethnic minorities, patients with psychiatric co-factors, non-cigarette tobacco users, gender concerns, older smokers, and hospitalized smokers).

The strength of recommendations (I-III) and levels of evidence (A-D) are defined at the end of the Major Recommendations.

Key Points

Tobacco use is a chronic disease that needs ongoing monitoring and treatment. Monitor and treat all forms of tobacco use (e.g., smoking, spit tobacco, hookah, electronic cigarettes).

- ASK all patients about tobacco use and assess user's readiness to quit. Tobacco use status should be documented in the medical record *[IA]*.
- ADVISE all tobacco users to seriously consider making a quit attempt using a clear and personalized message. Advice as brief as 3 minutes is effective *[IA]*.

- ASSESS all tobacco users' willingness to make a quit attempt. If not yet ready to quit, offer motivational intervention using the 5 "R's" - relevance, risks, rewards, roadblocks, repetition *[IA]*.
- REFER patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco treatment program. Alternatively, health care providers can directly provide the following treatment *[IA]*.

Treatment Options

- ASSIST those ready to make a quit attempt *[IA]*:
  - Set a quit date. Quit date abstinence is a strong predictor of long term success.
  - Give advice on quitting and provide supplementary materials.
  - Prescribe pharmacologic therapy as appropriate. Nicotine replacement therapies, bupropion hydrochloride, and varenicline have been proven effective.
- ARRANGE follow-up either with phone call or office visit *[IA]*.
  - Prevent relapse by congratulating successes and reinforcing reasons for quitting.
  - Assess any difficulties with pharmacologic therapy.

Definitions:

Strength of Recommendations

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Clinical Algorithm(s)

An algorithm titled "Clinician's Actions to Help Patients Quit Smoking" is provided in the original guideline document.

Scope

Disease/Condition(s)

Tobacco dependence

Guideline Category

Counseling

Screening

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Pediatrics

Intended Users

Health Care Providers

Health Plans

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide a framework for care providers to assist patients in quitting tobacco use

Target Population

Adult and adolescent tobacco users

Interventions and Practices Considered

Screening

1. Assessment and documentation of tobacco use status
2. Assessment of readiness to quit

Treatment

1. Advice and counseling:
    - Brief clinic intervention model known as "3 A's and Refer" model: Ask, Advise, Assess, and Refer
    - Motivational intervention using "5 R's": Relevance, Risks, Rewards, Roadblocks, Repetition
2. Pharmacotherapy
    - Nicotine replacement (transdermal patch, lozenge, gum, nasal spray, inhaler)
    - Bupropion hydrochloride SR (Zyban®)
    - Varenicline (Chantix®)
    - Clonidine
    - Nortriptyline
3. Follow-up to prevent relapse
4. Assessment of difficulties with pharmacologic therapy

Major Outcomes Considered

Efficacy of treatment as evidenced by tobacco use cessation rates

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The update of literature beyond the search performed for the initial University of Michigan Health System (UMHS) Smoking Cessation Guideline began with the literature search performed to produce "Treating Tobacco Use and Dependence 2008 Update," US Public Health Service (PHS), May 2008. The guideline team then updated the PHS literature search through a Medline search of literature June 2007 – February 2011. This search used the major keywords of: smoking [prevention, cessation, & control], tobacco use [prevention treatment, control, & rehabilitation]. The search was restricted to literature that was also referenced: as guidelines, controlled trials, or cohort studies; as studies of humans; and as published in English. Specific searches were performed for the topics: counseling (includes assessment, transtheoretical model); pharmacologic treatment; other therapies (including complementary/alternative); electronic cigarette (ecigarette); pregnancy; adolescents; older adults; racial/ethnic minority differences; gender differences; prevention (includes physician interactions with children and adolescents, counseling about having a smoke free home, and avoiding environmental tobacco smoke including residue); and other smoking cessation guidelines, controlled trials, or cohort studies not included above.

The literature search for this project was conducted prospectively. The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was a single cycle.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of evidence that reflect the best available literature in support of an intervention or test:

- Randomized controlled trials
- Controlled trials, no randomization
- Observational trials
- Opinion of expert panel

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Conclusions were based on prospective randomized controlled trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Drafts of this guideline were reviewed in clinical conferences and by distribution for comment within departments and divisions of the University of Michigan Medical School to which the content is most relevant: Family Medicine, General Internal Medicine, Pediatric Medical Surgical Joint Practice Committee, and Mott Executive Committee. The Executive Committee for Clinical Affairs of the University of Michigan Hospitals and Health Centers endorsed the final version.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Conclusions were based on prospective randomized controlled trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Effective interventions and strategies for health care providers to assist patients in quitting tobacco use

Potential Harms

Side Effects of Medications

- *Transdermal nicotine patch* - Skin reactions such as pruritus, edema, rash; sleep disturbance
- *Nicotine lozenge* - Headache, diarrhea, flatulence, heartburn, hiccups, nausea, coughing, sore throat, and upper respiratory infection

(occurring in >5% of patients)

- *Nicotine gum (polacrilex)* - Jaw fatigue, hiccups, belching, and nausea
- *Nicotine nasal spray* - Nasal irritation/rhinorrhea (98% of patients), sneeze, cough. Decreased severity of effects after first week.
- *Nicotine inhaler* - Cough, mouth and throat irritation. Use with caution in patients with reactive airway disease.
- *Bupropion hydrochloride SR (Zyban®)* - Insomnia, dry mouth, nausea and seizures (1 in 1000)
- *Varenicline (Chantix®)* - Caution with poor renal function. Adjust dose with creatinine clearance (CrCl) <30. Nausea, insomnia, and unusual dreams. Neuropsychiatric symptoms: behavior changes, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. A recent meta-analysis of 14 double-blind randomized controlled trials involving over 8000 patients showed that varenicline was associated with a significantly increased risk of serious adverse cardiovascular events compared with placebo, with an odds ratio (OR) of 1.72 (1.09 - 2.71).
- *Nortriptyline* - Dry mouth, sedation, shaky hands, constipation, urinary retention. Use with caution in patients over 65.
- *Clonidine* - Dry mouth, sedation, dizziness, constipation

Several studies have addressed the safety of nicotine replacement therapy or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of nicotine replacement therapy (NRT) than with smoking itself. Studies have not demonstrated the efficacy of pharmacotherapy in pregnancy. The U.S. Food and Drug Administration (FDA) pregnancy risk categories are: bupropion - category C, nicotine transdermal, spray and inhaler - category D, nicotine gum - category C, varenicline – category C.

Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.

Contraindications

Contraindications

- Bupropion hydrochloride SR (Zyban®) is contraindicated in patients with seizure disorder, major head trauma, eating disorders, and in patients on Wellbutrin® or monoamine oxidase (MAO) inhibitors.
- Nortriptyline (Pamelor®) is contraindicated with MAO inhibitors and during recovery from acute myocardial infarction (MI).
- Clonidine is contraindicated for transdermal use if on anticoagulation therapy, severe cardiovascular disease, or hemodynamically unstable.
- Since varenicline is a nicotine agonist, it should NOT be used in conjunction with nicotine replacement therapy (NRT) products.

Qualifying Statements

Qualifying Statements

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

Implementation of the Guideline

Description of Implementation Strategy

Organizing a Health Care Site to Support Smoking Cessation Efforts

Successful intervention programs require coordinated efforts at a health care site. Several clinic personnel may be involved in operational steps of "Asking, Advising, Assessing, and Referring." Clinicians should help their clinics develop a coordinated plan of tasks and who will perform them. Some specific areas for planning include:

Record tobacco use status. Institute an office system to identify all tobacco users:

- Identify where tobacco use status will be recorded. Options include making tobacco status part of vital signs, placing tobacco status stickers

on charts, or including tobacco status on a section of the Problem Summary List.
- Determine who will routinely ask and record the information.
- Instruct staff regarding their roles in documentation.
- Reinforce the value of the documentation.

Follow-up for quitting tobacco use. Develop a system and assigned role(s) at the health care site to:

- Ensure the availability of patient education materials on quitting tobacco use.
- Establish procedures for clinicians to provide a designated follow-up person with information on patients who are setting quit dates. Coordinate follow-up phone calls in conjunction with quit dates.
- Patients prescribed bupropion or varenicline should be contacted 2 weeks after starting medications to assess for neuropsychiatric side effects.
- Provide follow-up cessation counseling as needed at subsequent clinic visits.
- Refer patients to more intensive counseling programs for quitting tobacco use, as needed.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

The guideline was adapted from the Public Health Service guideline: Treating tobacco use and dependence: 2008 update. Clinical practice guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

Date Released

1998 Sep (revised 2012 Mar)

Guideline Developer(s)

University of Michigan Health System - Academic Institution

Source(s) of Funding

University of Michigan Health System

Guideline Committee

Tobacco Treatment Guideline Team

Composition of Group That Authored the Guideline

Team Leader: David C. Serlin, MD, Family Medicine

Team Members: Michael A. Clay, MD, General Internal Medicine; R. Van Harrison, PhD, Medical Education; Linda A. Thomas, MS, CTTS-M, UMHS Tobacco Consultation Service

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Financial Disclosures/Conflicts of Interest

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

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David C Serlin, MD	(none)	
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Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Smoking cessation. Ann Arbor (MI): University of Michigan Health System; 2006 Aug. 12 p. [1 reference]

Guideline Availability

Electronic copies: Available from the University of Michigan Health System Web site .

Availability of Companion Documents

The following are available:

- Tobacco treatment (2012). CME course. Available from the University of Michigan Health System (UMHS) Web site .
- How to help your patients quit tobacco use 2012. Pocket card. Ann Arbor (MI): University of Michigan Health System; 2012. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the UMHS Web site .

Patient Resources

The following are available:

- How to quit smoking. Ann Arbor (MI): University of Michigan Health System; 2012 Feb. 4 p. electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System (UMHS) Web site . Arabic, Chinese, French, Korean, Russian, and Spanish translations are also available from the UMHS Web site .
- Nicotine replacement products. Ann Arbor (MI): University of Michigan Health System; 2011 Oct. 2 p. Available in PDF from the UMHS Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on January 11, 2002. The information was verified by the guideline developer as of February 8, 2002. This summary was updated by ECRI on November 10, 2006. The updated information was verified by the guideline developer on December 12, 2006. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on February 5, 2008, following the U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was updated by ECRI Institute on July 20, 2009 following the U.S. Food and Drug Administration advisory on Varenicline and Bupropion. This summary was updated by ECRI Institute on July 15, 2011 following the U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was completed by ECRI on June 7, 2012. This summary was updated by ECRI Institute on January 14, 2013 following the revised U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was updated by ECRI Institute on April 8, 2015 following the U.S. Food and Drug Administration advisory on Chantix (varenicline).

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